IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

BRADLEY COOPER, Individually and on Behalf of all Others Similarly Situated; TODD LABAK,

Plaintiffs,

v.

THORATEC CORPORATION; GERALD F. BURBACH; TAYLOR C. HARRIS; and DAVID SMITH,

Defendants.

/

No. 14-CV-0360 CW

ORDER DISMISSING SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND

Plaintiffs Bradley Cooper and Todd Labak bring this putative class action lawsuit, on behalf of themselves and all other persons who bought or otherwise acquired the common stock of Thoratec Corporation (the Class Members) between May 11, 2011 and August 6, 2014 (the Class Period). This action claims violations of the Securities Exchange Act of 1934 and the Rules promulgated thereunder, against Defendants Thoratec Corporation, Gerhard Burbach, Taylor Harris and David Smith.

Plaintiffs allege that, during the Class Period, Defendants induced Class Members to acquire Thoratec stock at artificially inflated prices, by making knowingly and intentionally misleading and false statements regarding the safety of HeartMate II (HMII), one of Thoratec's medical device products. On January 24, 2014, Plaintiffs filed a complaint and on June 20, 2014, they filed a first amended complaint (1AC). Defendants moved to dismiss and, on November 26, 2014, the Court granted that motion with leave to amend. On January 20, 2015, Plaintiffs filed a second amended

complaint (2AC) and Defendants now move to dismiss the 2AC in its entirety. Plaintiffs oppose the motion. Having considered the papers filed by the parties, the Court GRANTS the motion to dismiss, without leave to amend.

BACKGROUND

I. Request for Judicial Notice

Defendants ask that the Court take judicial notice of several documents. Defendants' Request for Judicial Notice (RFJN), Docket No. 52, Exs. 1-30; Docket No. 66, Exs. 31-45. "[A] court may take judicial notice of matters of public record." Sami v. Wells Fargo Bank, 2012 WL 967051, at *4 (N.D. Cal.)(citation omitted).

> As a general rule, we may not consider any material beyond the pleadings in ruling on a Rule 12(b)(6) motion. We may, however, consider materials that are submitted with and attached to the Complaint. We may also consider unattached evidence on which the complaint necessarily relies if: (1) the complaint refers to the document; (2) the document is central to the plaintiff's claim; and (3) no party questions the authenticity of the document. Pursuant to Federal Rule of Evidence 201, we may also take judicial notice of matters of public record, but not of facts that may be subject to reasonable dispute. More specifically, we may not, on the basis of evidence outside of the Complaint, take judicial notice of facts favorable to Defendants that could reasonably be disputed.

United States v. Corinthian Colleges, 655 F.3d 984, 998-99 (9th Cir. 2011).

Plaintiffs do not object to exhibits two through four, seven through nine, eleven through thirteen, fifteen, and twenty through thirty; however, they state that the exhibits should only be considered "for the limited purpose of what they state and when they are filed." Docket No. 61 at 2. Accordingly, the Court takes judicial notice of the above exhibits for that purpose.

Plaintiffs object to exhibits five, six, ten, fourteen, and thirty-one through forty-five in their entirety, because "they are not referred to or relied upon in the [2AC] and are not the type of documents that should be the subject of judicial notice." Id.

Exhibit five is a copy of the dictionary entry for "person-years" from Stedman's Medical Dictionary (28th edition 2006). Id. at 1467. Defendants offer the term as one component of determining the rate of thrombosis. Because Plaintiffs refer extensively to the rate of thrombosis, and refer to studies that use the term, the Court will take judicial notice of this medical term.

Exhibit six is the September 6, 2013 Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) "Initial Analyses of Suspected Pump Thrombosis." Plaintiffs correctly state that this study is not directly incorporated into the 2AC, which instead refers to the INTERMACS "analysis of pump thrombosis in the HeartMate II left ventricular assist device," which was published online on November 27, 2013. RFJN, Ex. 9. However, exhibit six presents the preliminary analysis of the same data upon which exhibit nine relies, and exhibit nine refers to exhibit six. Accordingly, the Court will take judicial notice of this exhibit.

Exhibit ten consists of letters sent to the editors of the New England Journal of Medicine (NEJM). These letters were sent to the NEJM in response to a study published therein that reported increasing rates of thrombosis associated with HMII. Plaintiffs argue that the letters are Defendants' "attempt to prove that the NEJM study was not reliable. The exhibit itself is an opinion of

an author -- not a fact, which will be highly contested throughout the litigation, but also whose authentication may be disputed." Docket No. 61 at 7. While Defendants counter that the letters are not offered to dispute the reliability of the NEJM study, but rather to show that "practitioners from other centers reported varying levels of thrombus for their patients," the Court is persuaded by Plaintiffs' argument. Accordingly, Defendants' request for judicial notice of exhibit ten is denied.

Exhibit fourteen is a January 2014 article published in the Journal of Heart and Lung Transplantation (JHLT). One of the doctors who wrote this article also published a 2012 article on the rate of thrombosis associated with a competitor's device, HeartWare, and Plaintiffs refer to that article in the 2AC. See 2AC ¶¶ 55 and 167. The 2014 article, according to Defendants, is the "completed analysis of an earlier 'update' of the study" Plaintiffs refer to in the 2AC. Defendants offer the document to show that the JHLT study reported a thrombus rate of 0.08 events per patient-year for the HeartWare device. Defendants' argument is unpersuasive; Defendants offer the document for the purpose of establishing that the HeartWare device had a thrombosis rate similar to that of the HMII. That is a disputed fact. Accordingly, the Court denies Defendants' request for judicial notice of this exhibit.

Exhibits thirty-one through forty-five are included in Defendants' "Supplemental Request for Judicial Notice in Support of their Reply." Docket No. 65. Defendants offer the exhibits to respond to two arguments raised in Plaintiffs' opposition. Plaintiffs move to strike this supplement, arguing that Defendants

did not seek leave from the Court to file a supplement to their reply. Moreover, they argue that the supplement is Defendants' attempt to introduce new evidence.

The Court does not rely on these documents in reaching its conclusion; thus it denies the supplemental request for judicial notice.

II. Facts

The following facts are taken from Plaintiffs' 1AC, 2AC and documents of which the Court takes judicial notice. These facts are taken as true for the purposes of this order.

Thoratec is a medical device corporation that researches, develops, manufactures and markets devices for circulatory support and vascular graft applications. 2AC ¶ 2. It develops and manufactures the HMII, a heart pump used to support heart function and blood flow in people who have heart failure. Id. ¶¶ 34, 35. Defendants are high-level executives who were employed by Thoratec during the Class Period.[1]

Thoratec received Food and Drug Administration (FDA) approvals for HMII in April 2008 and January 2010, after approximately five to seven years of testing for safety and effectiveness. Id. ¶¶ 41, 43. In its summary of safety and effectiveness for the device, the FDA published data indicating the HMII had a two percent rate of thrombus, also called

[1] During the Class Period, Defendant Gerhard Burbach was the President and Chief Executive Officer (CEO); Defendant Taylor C. Harris became the Chief Financial Officer and Vice President on October 11, 2012; and Defendant David V. Smith was the Executive Vice President and Chief Financial Officer between December 2006 and July 2011.

thrombosis, a potential complication when blood clots in the device. Id. ¶ 41.

Plaintiffs allege that, during the Class Period, the number of HMII-related incidents of thrombosis increased "dramatically." Id. ¶ 78. The FDA collects, for devices it regulates, data related to Serious Adverse Effects (SAEs) as reported by manufacturers and importers as well as health care professionals, patients and consumers. Id. ¶ 80. It collects this data in a public database, known as the Manufacturer and User Facility Device Experience database (MAUDE). Id. Plaintiffs allege a dramatic increase of SAEs involving thrombosis between 2010 and 2014. In 2010, there were fifty-six SAEs involving thrombosis; 200 in 2011; 487 in 2012; 473 in 2013; and 264 in the first half of 2014. Id.

Plaintiffs also allege that the sales of the HMII were only moderately increasing in contrast to the number of thrombosis-related events. According to Plaintiffs, revenue from sales of the HMII were $333 million in 2010; $366 million in 2011; $434 million in 2012; $444 million in 2013; and $212 million in the first half of 2014. Id. ¶ 82.

In addition to the MAUDE reports, a study discussing HMII's increasing thrombosis rates published on November 27, 2013 in the New England Journal of Medicine (NEJM) reported, "Starting in approximately March 2011, the occurrence of confirmed pump thrombosis at 3 months after implantation increased from 2.2% . . . to 8.4% . . . by January 1, 2013." Id. ¶ 128. This report covered three centers where HMIIs were implanted. Id. The finding was reported in the next day's issue of the New York

Times. Id. ¶ 194. Also on November 27, 2013, the Journal of Heart and Lung Transplantation published a study titled "Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) analysis of pump thrombosis in the HeartMate II left ventricular device," which likewise reported an increase in the rate of HMII-related thrombosis. Id. ¶ 130. The INTERMACS study reported that "freedom from device exchange or death due to thrombosis went from 99% at 6 months in 2009 to 94% in 2012." Id. Plaintiffs allege that, on November 29, 2013, after the two studies and the news article were published, Thoratec stock decreased by six and one half percent. Id. ¶ 129.

Plaintiffs allege that, prior to the publication of the NEJM article and INTERMAC results, Defendants were aware of the thrombosis issues with HMII. Id. ¶ 134. They also allege that, in spite of their knowledge to the contrary, Defendants continued to market the device as having low thrombosis rates. According to Plaintiffs, this deception gave HMII a competitive edge over the HeartWare device, which entered the market a year after HMII did. Id. ¶¶ 47-57.

In the complaint, Plaintiffs allege that twenty-five statements made by Defendants were false or misleading regarding the safety of HMII, leading to an inflated stock price during the Class Period. Plaintiffs allege that, as a result of Defendants' deception, Class Members were harmed when the stock price declined following the publication of the NEJM article and INTERMACS results. In addition, Plaintiffs allege that, during the Class Period, Defendants engaged in insider trading. Id. ¶¶ 86-87. They allege that, "as the class period went on, and Defendants

gained more knowledge of the increased thrombosis rate, they continued to dump shares at alarming rates." Id.

Plaintiffs assert, on behalf of themselves and other similarly situated individuals, two causes of action against all Defendants: (1) violations of § 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder; and (2) violations of § 20(a) of the Exchange Act.

LEGAL STANDARD

A complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). The plaintiff must proffer "enough facts to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id.

In considering whether the complaint is sufficient to state a claim, the court will take all material allegations as true and construe them in the light most favorable to the plaintiff. Metzler Inv. GMBH v. Corinthian Colls., Inc., 540 F.3d 1049, 1061 (9th Cir. 2008). The court's review is limited to the face of the complaint, materials incorporated into the complaint by reference, and facts of which the court may take judicial notice. Id. However, the court need not accept legal conclusions, including "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements." Iqbal, 556 U.S. at 678 (citing Twombly, 550 U.S. at 555).

When granting a motion to dismiss, the court is generally required to grant the plaintiff leave to amend, even if no request to amend the pleading was made, unless amendment would be futile. Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv. Inc., 911 F.2d 242, 246-47 (9th Cir. 1990). However, the court has discretion to deny leave to amend, especially where a plaintiff has previously amended the complaint. See Allen v. City of Beverly Hills, 911 F.2d 367, 373-74 (9th Cir. 1990).

"In addition to the pleading requirements of Rule 8, there are more demanding pleading requirements for certain causes of action, especially securities fraud." In re Rigel Pharm., Inc., Sec. Litig, 697 F.3d 869, 876 (9th Cir. 2012). Rule 9(b) provides, "In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). The allegations must be "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." Semegen v. Weidner, 780 F.2d 727, 731 (9th Cir. 1985). Statements of the time, place and nature of the alleged fraudulent activities are sufficient, provided the plaintiff sets forth "what is false or misleading about a statement, and why it is false." In re GlenFed, Inc., Sec. Litig., 42 F.3d 1541, 1548 (9th Cir. 1994), superseded by statute on other grounds, Private Securities Litigation Reform Act (PSLRA) of 1995, Pub. L. No. 104-67.

In 1995, Congress enacted the Private Securities Litigation Reform Act of 1995 (PSLRA), Pub. L. No. 104-67, which amends the Securities Exchange Act of 1934, 15 U.S.C. §§ 78a-78lll.

Although Rule 9(b) does not require that scienter be plead with particularity, see Concha v. London, 62 F.3d 1493, 1503 (9th Cir. 1995), the PSLRA does. See 15 U.S.C. § 78u-4(b)(2). The PSLRA provides that "the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). Because the instant action alleges violations of § 10(b), the "required state of mind" is defined by that section. See In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 975 (9th Cir. 1999), abrogated on other grounds by S. Ferry LP, No. 2 v. Killinger, 542 F.3d 776 (9th Cir. 2008). "This means that a plaintiff must provide, in great detail, all the relevant facts forming the basis of her belief." Silicon Graphics, 183 F.3d at 985. Factual allegations that are not based on plaintiffs' personal knowledge are allegations that are made on information and belief. Thus, for example, if a plaintiff's sole basis for an allegation is a statement from a non-plaintiff witness, that allegation is made on information and belief, and the plaintiff must plead all facts on which that belief is based. See id. at 985, 998 n.21. This does not mean, however, that a plaintiff must, for each allegation plead on information and belief, state every fact possessed that is in any way related to the allegation. Id. at 999.

Section 10(b) of the Securities Exchange Act makes it unlawful for any person to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and

regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b); see also 17 C.F.R. § 240.10b-5 (Rule 10b-5). Rule 10b-5(b) clarifies that it is "unlawful for any person, directly or indirectly, . . . to make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading[.]" 17 C.F.R. § 240.10b-5(b). The PSLRA thus requires that a plaintiff plead with particularity "facts giving rise to a strong inference that the defendant acted with," at a minimum, deliberate recklessness. See 15 U.S.C. § 78u-4(b)(2); Silicon Graphics, 183 F.3d at 977. Facts that establish a motive and opportunity, or circumstantial evidence of "simple recklessness," are not sufficient to create a strong inference of deliberate recklessness. See id. at 979. In order to satisfy the heightened pleading requirement of the PSLRA for scienter, a plaintiff "must state specific facts indicating no less than a degree of recklessness that strongly suggests actual intent." Id.

DISCUSSION

I. Order Granting the Motion to Dismiss 1AC

In the November 26, 2014 Order granting Defendants' motion to dismiss the 1AC, the Court discussed several reasons why the 1AC was deficient. First, it found that the 1AC failed to allege facts sufficient to support the allegations that any statement with regard to the rate of thrombosis made by Defendants was false. Plaintiffs had alleged that the number of thrombosis events had increased during the Class Period, but did not state facts sufficient to support the allegation that the rate of thrombosis had increased.

Second, the Court stated that the 1AC's allegations with regards to statements in financial disclosures, statements of corporate optimism, opinions, forward-looking statements, and the statements of third parties were non-actionable. The Court also found that statements which referred to the results of specific studies were non-actionable because Plaintiffs did not allege that Defendants mischaracterized the results of those studies.

Third, the Court found that allegations that relied solely on the MAUDE data, data that the FDA specifically warned was not to be used to establish the rates of events, was unavailing. Plaintiffs did not state facts sufficient to support their allegation that Defendants were aware of any internal data that showed an increase in the rate of thrombosis. Likewise, Plaintiffs failed to allege facts sufficient to show that, even if the rate of thrombosis was increasing, Defendants' statements about thrombosis were false or misleading when made.

The Court also found that Plaintiffs failed to plead adequate facts to support scienter and loss causation. Plaintiffs did not state facts as to the content or timing of the alleged internal reports that were needed to support a strong inference of deliberate recklessness. Furthermore, Plaintiffs' reliance on the statements of Confidential Witnesses was unavailing because they failed to allege facts to support that these witnesses were in a position to have personal knowledge that Defendants knew about actual increases in the rate of thrombosis.

Plaintiffs also alleged a violation of § 20(a) of the Exchange Act, but that cause of action failed because they failed to allege a § 10(b) cause of action. Plaintiffs were given leave

to amend the complaint if they could do so without contradicting prior pleadings.

II. Changes in the 2AC

At the hearing on the motion to dismiss the 1AC, the Court instructed that if Plaintiffs filed an amended complaint, they must also submit a redlined copy of the 1AC with their 2AC. However, to the extent that Plaintiffs moved paragraphs around, the Court permitted them submit a notice of the changes made in the 2AC, which Plaintiffs have done. Docket No. 50.

In the notice, they state the following aspects of the complaint have changed: (1) the Class Period has shifted from April 29, 2010 through November 27, 2013 to May 11, 2011 through August 6, 2014; (2) Defendant Roxanne Oulman has been dropped as a party; (3) Plaintiff Todd Labak has been added as a named Plaintiff because Plaintiff Bradley Cooper did not purchase any Thoratec stock during the amended Class Period; (4) the 2AC focuses on statements made by Defendants that the thrombosis rates were maintained at two to three percent, or that thrombosis rates were consistently maintained at clinical trial rates; (5) statements made by Defendants comparing HMII and the HeartWare product support scienter instead of stand-alone actionable statements; and (6) allegations based on SEC filings have been removed.

Like the 1AC, Plaintiffs' 2AC alleges that, during the Class Period: (1) the rate of thrombosis caused by HMII increased; (2) Defendants knew of this increase; (3) they failed to disclose the increase; and (4) they knowingly made misleading and/or false statements to investors. Plaintiffs allege that, as a result, the

Class Members incurred losses when the deception was revealed to the market. The Court now turns to the causes of action.

III. First Cause of Action: Violation of § 10(b) of the Securities Exchange Act

To state a claim under § 10(b) and Rule 10b-5(b), Plaintiffs must allege: "(1) a misrepresentation or omission of material fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss." In re Gilead Sciences Sec. Litig., 536 F.3d 1049, 1055 (9th Cir. 2008). For each statement that Plaintiffs allege to be false or misleading, the PSLRA requires that the complaint state "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1).

Plaintiffs identify twenty-five statements that they allege are actionable under § 10(b). The Court will discuss these statements in two groups: (1) statements made prior to November 27, 2013, which is when Plaintiffs allege that the "truth" was revealed about the increased rate of thrombosis; and (2) statements made after November 27, 2013.

A. Pre-November 27, 2013 statements

Plaintiffs identify fifteen statements made by Defendants prior to November 27, 2013 that were allegedly false and misleading. They argue Defendants knew, based on internal data, that the rate of thrombosis was significantly higher than the two to three percent rate that was established during the clinical trials.

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1. Statements that refer to rates of thrombosis

Plaintiffs allege that, near the beginning of the Class Period, Defendant Smith stated, "And you can see that we have very low rates [of thrombosis associated with the HMII] here, between 0.02 and 0.03, with the Bridge and the DT trials." 2AC ¶ 90. Plaintiffs allege similar statements made by Defendant Burbach between September 13, 2011 and July 31, 2013, as well as by Defendant Harris between September 22, 2011 and September 19, 2012. See id. ¶¶ 93, 96, 100, 103, 106, 109, 112, 115, 118, 119, 122, 123, 126 and 127. Plaintiffs allege that these statements were false and misleading when made because Defendants knew that "the thrombosis rate at the time of the statement had risen well above that level" and that Defendants, according to the statements of Confidential Witnesses, "would have been made aware of the increase in events based on the Company's record keeping of SAEs." Id. ¶¶ 91-92; see id. ¶¶ 94-95, 97-98, 101-102, 104-105, 107-108, 110-111, 113-114, 116-117, 118-121, 122, 123 and 127. Plaintiffs refer to the MAUDE data to establish that Defendants were aware of the increasing rate of thrombosis. In the Order dismissing the 1AC, the Court stated,

> Plaintiff's allegations based on MAUDE data are unavailing. The MAUDE front page includes the following disclaimer: "Although MDRs [medical device reports] are a valuable source of information, the passive surveillance system has its limitations, including the submission of incomplete, inaccurate, untimely, unverified or biased data." RFJN, Ex. 1. Furthermore, it states, "MDR data alone cannot be used to establish the rates of events, evaluate a change in event rates over time or compare rates between devices." Id. An increase in the number of events does not translate into an increased rate if the number of devices used has increased also. Despite this warning, Plaintiff relies on this data as evidence that the actual rates of thrombosis were increasing, and that the Defendants knew the rates were increasing because they were aware of the MAUDE data. Plaintiff does

> not allege that any internal data on the actual rates of thrombosis demonstrated an increase.

November 26, 2014 Order at 23.

The 2AC suffers from the same deficiency. In the 2AC, Plaintiffs state, "The FDA's [MAUDE] database demonstrates that during the Class Period, SAE's involving thrombosis were increasing and being reported to Defendants at a much greater rate than HeartMate II devices were being implanted." Id. ¶ 80. They go on to assert, based on the MAUDE data, "The amount of adverse events involving thrombosis that were reported to Defendants during the Class Period" was increasing. Id.

As discussed in the previous order, the MAUDE data cannot be used to establish the rates of SAEs, including thrombosis. Yet, Plaintiffs continue to rely on the MAUDE data to indicate that the number and rates of thrombosis were actually increasing. While Plaintiffs also provide what they purport to be only a modest increase or no change at all in the sales revenues of HMII, see id. ¶¶ 82-84, as discussed below, sales revenues do not sufficiently correlate with the number of devices in use or the length of time that the devices have been implanted.[2]

As Defendants point out, the rates of thrombosis -- including the clinical trial rate, which Plaintiffs use as their baseline rate of two to three percent, see id. ¶ 100 –- are expressed in

[2] In their opposition, Plaintiffs admit that they "were unable to calculate unit volume vs. sales consistently throughout the Class Period because Defendants only disclosed the unit volume number on three occasions during the Class Period, but clearly this information was known to Defendants. If the data would have supported their position in their motion to dismiss, they would have submitted it here." Docket No. 60 at 17 n.12.

terms of patient-years, which accounts not just for the number of devices that have been implanted, but the number of years the devices have been in place. See RFJN, Ex. 5. Plaintiffs downplay this issue, stating that "a reasonable investor would believe that the rates were maintained at 2% -- regardless of how Defendants calculate them." Pls.' Opp., Docket No. 60 at 13. But Plaintiffs fail to account for the fact that a reasonable investor would calculate a change in rates using the same formula as that used to calculate the baseline rate.

Thus, the alleged false and misleading statements that refer to an actual change in thrombosis rates based on the MAUDE data and sales revenue cannot support a claim for violation of § 10(b). Accordingly, the Court shall disregard these statements (2AC ¶¶ 90, 93, 96, 100, 103, 106, 109, 112, 115, 118, 119, 122, 123, 126 and 127) when considering the sufficiency of the 2AC.

2. Statements that refer to published studies

Furthermore, several statements made by Defendants that Plaintiffs allege were false or misleading when made refer to rates of thrombosis as published or as a result of clinical trials or other studies. See id. ¶ 90 ("with the Bridge and the DT trials"), ¶ 96 ("very low thrombus rate in the clinical trial environment . . . [t]hat's been well documented and published"); ¶ 100 ("low rates . . . from an array of published articles"); ¶ 103 ("consistently low adverse event rates as published and presented in a variety of peer-reviewed publications"); ¶ 106 ("lowest published rates of adverse events"); ¶ 109 ("[t]here's obviously been a lot of literature . . . showing HeartMate II thrombus rates in the low single-digits"); ¶ 112 ("when we look at

national level data spanning the full spectrum of centers, the rates of thrombus . . . are very consistent with the clinical trial"); and ¶ 119 ("lowest rates of some critical adverse events that have been published in peer-reviewed literature"). In the order dismissing the 1AC, the Court held that statements which referred to specific studies were non-actionable unless Plaintiffs alleged that Defendants mischaracterized the results of those studies. See November 26, 2014 Order at 21. Plaintiffs do not so allege. Thus, these statements (2AC ¶¶ 90, 96, 100, 103, 109, 112 and 119) are non-actionable for this reason also.

3. Statements unrelated to thrombosis

In addition, several statements Plaintiffs allege were misleading did not refer to thrombosis rates at all. Plaintiffs allege that, prior to November 27, 2013, Defendants made five statements about the number of units sold while failing to disclose that thrombosis rates were increasing. See id. ¶¶ 118, 122, 123, 126 and 127. For example, Plaintiffs allege that, on May 1, 2012, Defendant Burbach, in a press release about Thoratec's 2012 first quarter financial results, touted HMII's "broad-based . . . unit growth of 32% in both the U.S. and international markets." Id. ¶ 118. Plaintiffs allege that "Burbach failed to disclose the fact that there was a 220% increase in the amount of thrombosis related events reported to the Company for this same quarter[.]" Id. As discussed above, Plaintiffs do not allege facts sufficient to support the allegation that there was an actual increase in rates or that the Company was aware of those rates. Thus, these statements (2AC ¶¶

118, 122, 123, 126 and 127) are non-actionable for this reason as well.

B. Post-November 27, 2013 statements

Plaintiffs allege that, after November 27, 2013, Defendants made ten statements that were false or misleading when made. See id. ¶¶ 138, 140, 143, 146, 149, 151, 154, 156, 159 and 162. Plaintiffs allege that, in these statements, Defendants downplayed the seriousness of the thrombosis problem related to HMII.

1. Statements that refer to the rate of thrombosis

Plaintiffs allege that, on March 3, 2014, Defendant Harris stated, "Our internal data also mirrors the broad INTERMACS' database which showed an overall lower rate of complications than what were shown in the New England Journal of Medicine article." Id. ¶ 154. Plaintiffs concede that the INTERMACS database actually demonstrated a lower rate of thrombosis than was reported in the NEJM article, but claim the statement was false or misleading because the INTERMACS database "still demonstrated a rate that was dramatically more than the pre-approval clinical rate that Defendants reported prior to the NEJM study." Id. ¶ 155. It is not clear what is false or misleading about Defendant Harris's statement. A statement of "lower" rate could be proven false, but Plaintiffs never allege that Thoratec's internal data was inconsistent with the INTERMACS database or that Defendants mischaracterized the INTERMACS database.

This flaw can be found in several of Plaintiffs' allegations. See id. ¶ 138 ("our internal data is consistent with the data that's in the . . . INTERMACS Registry that's published in the Journal of Heart and Lung Transplant"); ¶ 140 ("we've seen

stabilization in that rate [referring to the INTERMACS database rates]"); ¶ 143 ("[O]ur internal data is very consistent with the INTERMACS registry"); ¶ 146 ("moreover our more recent data shows stabilization in thrombosis rates . . . in contrast to the still increasing rates suggested by [NEJM article]"); ¶ 149 ("we expect additional clinical data . . . will be released . . . including results from centers experiencing lower levels of thrombosis"); ¶ 151 ("there are centers that have very low rates . . . and there are centers who have higher rates of thrombosis"); and ¶ 156 ("as we've looked at our internal data . . . we saw a stabilization over a year ago . . . if that trend holds then that will start to filter through the larger public data sources like the INTERMACS registry"). Plaintiffs have not alleged that any of these statements misrepresent the INTERMACS data or Thoratec's internal data.

Plaintiffs also allege that, on May 13, 2014, Defendant Burbach made the following statement: "The full universe of adverse events, stroke is down, bleeding is down, infection is down as you look at the HeartMate II in this time period where you saw thrombus up." Id. ¶ 162. Plaintiffs allege that this statement was false or misleading because "adverse events due to thrombosis were not down." Id. ¶ 163. Yet, Defendant Burbach clearly refers to the perception that the rate of thrombosis may have gone up. Plaintiffs do not allege any facts to support the inference that this statement was false.

Thus, the Court shall disregard these statements (2AC ¶¶ 138, 140, 143, 146, 149, 151, 154, 156 and 162) in considering the sufficiency of Plaintiffs' 2AC.

2. Revenue guidance

Plaintiffs allege that Defendants presented revenue guidance that was "unachievable when made" given the alleged rise in the rate of thrombosis. Id. ¶ 160.

> For a forward-looking statement such as . . . public guidance to constitute a material misrepresentation giving rise to Section 10(b) or Rule 10b–5 liability, a plaintiff must prove either "(1) the statement is not actually believed [by the speaker], (2) there is no reasonable basis for the belief, or (3) the speaker is aware of undisclosed facts tending seriously to undermine the statement's accuracy."

In re Oracle Corp. Sec. Litig., 627 F.3d 376, 388 (9th Cir. 2010) (citing Provenz v. Miller, 102 F.3d 1478, 1487 (9th Cir. 1996)).

Plaintiffs allege that, on May 6, 2014, Defendants Burbach and Harris "reiterated guidance of $520 million to $535 million in expected revenue in 2014" while downplaying the "seriousness of the rising thrombosis rates." Id. ¶ 159. Defendant Burbach allegedly stated, "The issue of thrombus remains a multifaceted adverse event with many contributing factors, and we believe that our internal initiatives combined with more recently released clinical data present a balanced view of the issue that will continue to advance the therapy." Id. Plaintiffs state that Defendant Burbach was misleading the investment community as to the extent of the "growing concern in the clinician community over the thrombosis rate." Id. ¶¶ 159-160.

Plaintiffs do not allege any facts to support the inference that Defendant Burbach's statement was a material misrepresentation. Even though Thoratec revised downward its revenue guidance in August 2014, Plaintiffs do not allege facts sufficient to support the inference that Defendant Burbach's May 2014 statement had no reasonable basis. Indeed, Plaintiffs allege

that, in August 2014, Defendant Burbach provided the following reason to explain why revenue for the company was less than expected:

> Beginning with adverse events, we believe perceptions about pump thrombosis since the late 2013 New England Journal of Medicine article along with greater scrutiny of clinical outcomes overall continues to be the largest factor impacting our business on a worldwide basis. While we expect that this would be a headwind during the first half of the year is now clearly the impact is persisting longer than expected. Specifically, we believe some implanting clinicians have become more selective in their patient evaluation criteria.

Id. ¶ 166.

This statement is far from Plaintiffs' characterization that, in August 2014, Defendants finally admitted "the truth." Indeed, this statement supports an inference that Defendants believed that the decrease in sales of HMII was due to clinicians choosing patients more carefully, not that they believed there was something inherently wrong with the device.

Furthermore, by the time this statement was made, Plaintiffs allege, the market had already learned the truth. Accordingly, they cannot allege that the information with regard to thrombosis was undisclosed. Thus, the Court shall disregard the May 6, 2014 statement (2AC ¶ 159) in considering the sufficiency of Plaintiffs' 2AC.

B. Scienter

Defendants argue that even if Plaintiffs' § 10(b) cause of action does not fail for the reasons discussed above, it fails because Plaintiffs fail to plead scienter adequately.

To plead scienter adequately under the PSLRA, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of

mind." 15 U.S.C. § 78u-4(b)(2)(A). A sufficient inference of scienter is "a strong inference that the defendant acted with an intent to deceive, manipulate, or defraud." Metzler, 540 F.3d at 1061. "The Supreme Court has emphasized that courts 'must review all the allegations holistically' when determining whether scienter has been sufficiently pled. The relevant inquiry is 'whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.'" Reese v. Malone, 747 F.3d 557, 569 (9th Cir. 2014) (citing Tellabs Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 323 (2007)); see also N.M. State Inv. Council v. Ernst & Young LLP, 641 F.3d 1089, 1095 (9th Cir. 2011).

Plaintiffs argue that Defendants acted knowingly or, at the very least, with reckless disregard for the truth when they made the statements discussed above. Based on information they received from Confidential Witnesses and their interpretation of the MAUDE database, Plaintiffs allege that Defendants were aware of internal reports that demonstrated a rise in thrombosis rates.

1. Deliberate recklessness

"Deliberate recklessness means that the reckless conduct 'reflects some degree of intentional or conscious misconduct.'" Reese, 747 F.3d at 569 (quoting S. Ferry LP, 542 F.3d at 782). "'[A]n actor is [deliberately] reckless if he had reasonable grounds to believe material facts existed that were misstated or omitted, but nonetheless failed to obtain and disclose such facts although he could have done so without extraordinary effort.'" Id. (quoting In re Oracle, 627 F.3d at 390).

In the order dismissing the 1AC, the Court found that, even assuming Plaintiffs' 1AC allegations were true, Defendants' statements did not give rise to a "strong inference" of deliberate recklessness. It stated,

> The 1AC's allegations about internal reports of an increasing rate of thrombosis fail to support an inference that the reports contained information that contradicted Defendants' statements when they were made. Further, absent allegations about the contents and timing of specific reports, Plaintiff's allegations based on MAUDE data, FDA recalls and adverse internal reports at best raise an inference of negligence, rather than a strong inference of deliberate recklessness. . . . Defendants contend that Plaintiff's only allegation of knowing misconduct is his vague and legally inadequate assertion that Defendants knew of unidentified negative internal reports. "[M]ere boilerplate pleadings [about unidentified negative internal reports] will rarely, if ever, raise a strong inference of deliberate recklessness." See Silicon Graphics, 183 F.3d at 984.

November 26, 2014 Order at 26-27.

The 2AC suffers from this same flaw. Plaintiffs rely on the fact that the MAUDE data was publicly available to show that an increase in the rate of thrombosis was "reported to" the Company. See, e.g., 2AC ¶ 92. As discussed above, however, Plaintiffs do not state facts sufficient to support the assertion that internal reports corresponded with the MAUDE data and, thus, contradicted

Defendants' public statements. Thus, these allegations cannot support a strong inference of deliberate recklessness.

2. Confidential Witnesses

Plaintiffs also rely on the statements of six Confidential Witnesses to support scienter.

> [C]onfidential witness statements may only be relied upon where the confidential witnesses are described with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged. Accordingly, the complaint must provide an adequate basis for determining that the witnesses in question have personal knowledge of the events they report. To determine whether the complaint has done so, we look to the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia.

Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 995 (9th Cir. 2009).

Plaintiffs rely on the same Confidential Witness statements alleged in the 1AC to support their 2AC allegation of scienter. The Court's previous order stated, "Plaintiff fails to allege facts sufficient to support that the confidential witnesses were in a position to have personal knowledge that Defendants knew of actual increases in the thrombosis rate." November 26, 2014 Order at 27. Accordingly, the Court found that the statements made by the Confidential Witnesses were insufficient to support scienter. The same is true here. Thus, the statements of the Confidential Witnesses cannot support a strong inference of scienter.

3. Motive

In addition, Defendants argue that Plaintiffs' motive allegations are insufficient to support a strong inference of scienter. "Facts showing mere recklessness or a motive to commit

fraud and opportunity to do so provide some reasonable inference of intent, but are not independently sufficient." Reese, 747 F.3d at 569. The Ninth Circuit has noted that where "Plaintiffs' allegation is essentially that these defendants possessed inside information on [the company's] imminent collapse . . . one would expect that they would have sold a good proportion of their holdings." In re Worlds of Wonder Sec. Litig., 35 F.3d 1407, 1427 (9th Cir. 1994) (citing and affirming the district court's ruling on this issue); see also Wenger, 2 F. Supp. 2d at 1251 ("stock sales alone cannot create a strong inference of scienter").

In the 2AC, Plaintiffs allege, "Defendants [Burbach and Harris] were motivated to disseminate materially false or misleading statements, as well as omit to disclose material information about the Device, including, but not limited to, the increase in the rate of thrombosis during the Class Period, in order to, inter alia, counter the rising competition from HeartWare . . . and personally profit from sales of stock in their portfolios during the Class Period." 2AC ¶ 186.

In the previous order, the Court found that these same allegations of motive were insufficient to support a strong inference of scienter because Plaintiffs did not allege "that the shares sold by Defendants during the Class Period were 'a good proportion' of their shares. Instead, Plaintiff only alleges that Defendants sold more shares during the Class Period than they had prior to the Class Period." November 26, 2014 Order at 30. The same is true here. It is true that, "along with other evidence of recklessness, information that compares stock sales before and after the Class Period may be indicative of scienter." Id. at 30-

31. However, as discussed throughout this Order, Plaintiffs fail to allege other evidence of recklessness.

Moreover, as Defendants point out, there is no evidence of a discrepancy between Defendant Harris's stock sales before and after the Class Period because Defendant Harris did not join the company as an officer until October 2012, well into the Class Period. See Mot. to Dismiss at 23. As to Defendant Burbach, Plaintiffs still fail to allege that he sold a "good proportion" of his shares. Instead, they allege only that during the Class Period Defendant Burbach sold "three times the amount of shares he sold prior to the Class Period." 2AC ¶ 87. While they state that he sold 196,702 shares prior to the Class Period, and 582,656 shares during the Class Period, Plaintiffs do not state what proportion of Defendant Burbach's total stock amount those shares comprised.[3]

Given these pleading defects, Plaintiffs have not alleged facts sufficient to support a strong inference of scienter. Accordingly, the cause of action for violating § 10(b) is dismissed in its entirety for this reason also.

C. Loss Causation

Finally, Defendants argue that Plaintiffs' § 10(b) cause of action fails because it does not plead loss causation.

[3] Plaintiffs allege that Defendant Burbach sold twenty-eight percent of his shares during the Class Period. However, they also allege that he owned 183,374 shares in May 2011 and 132,104 in November 2011. See Docket No. 60 at 21 n.16. As Defendants point out those calculations are inconsistent with Plaintiffs' allegation that Defendant Burbach sold over 500,000 shares during the Class Period. See Docket No. 63 at 10 n.11.

Pleading loss causation "requires a plaintiff to show that a misrepresentation that affected the integrity of the market price also caused a subsequent economic loss." Erica P. John Fund, Inc. v. Halliburton Co., 131 S. Ct. 2179, 2186 (2011).

> [T]he fact that a stock's price on the date of purchase was inflated because of [a] misrepresentation does not necessarily mean that the misstatement is the cause of a later decline in value. . . . [T]he drop could instead be the result of other intervening causes, such as changed economic circumstances, changed investor expectations, new industry specific or firm-specific facts, conditions, or other events. If one of those factors were responsible for the loss or part of it, a plaintiff would not be able to prove loss causation to that extent. This is true even if the investor purchased the stock at a distorted price, and thereby presumptively relied on the misrepresentation reflected in that price.

Id.

In its previous order, the Court stated that only if Plaintiff "properly alleged that Defendants made false statements about the rate of thrombosis, [could he] then . . . allege loss causation due to the NEJM's correction and the subsequent drop in the stock price." November 26, 2014 Order at 32-33. As discussed above, Plaintiffs have not made the requisite showing in the 2AC and, thus, cannot plead adequate loss causation. The 2AC's cause of action for a violation of § 10(b) is dismissed in its entirety for this reason as well.

For all the reasons discussed above, the 2AC fails to state a claim for violating § 10(b). Accordingly, the Court GRANTS Defendants' motion to dismiss this cause of action. Because Plaintiffs have previously been afforded leave to amend their complaint, the Court grants the motion to dismiss without leave to amend. See Allen, 911 F.2d at 373-74.

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IV. Second Cause of Action: Violations of § 20(a)

"[T]o prevail on their claims for violations of § 20(a), plaintiffs must first allege a violation of § 10(b) or Rule 10b-5." In re LDK Solar Sec. Litig., 584 F. Supp. 2d 1230, 1251-52 (N.D. Cal. 2008) (citing Lipton v. Pathogenesis Corp., 284 F.3d 1027, 1035 n.15 (9th Cir. 2002)).

As discussed above, Plaintiffs have failed to plead adequately a primary violation under § 10(b) and, hence, the Court must dismiss the § 20(a) cause of action. In addition, in the order dismissing the 1AC, the Court found that Plaintiffs failed adequately to impute "controlling persons" liability under § 20(a) because they did not allege adequately that Thoratec is liable for a § 10(b) violation. Accordingly, Plaintiffs could not allege that any of the individual Defendants are liable as "controlling persons." Plaintiffs did not cure this deficiency in the 2AC. Thus, the 2AC's cause of action for violating § 20(a) fails for this reason also.

For all the reasons stated above, Plaintiffs fail to state a claim for a violation of § 20(a); they have not plead sufficient facts to support their § 10(b) cause of action and they have not adequately plead that Thoratec is liable for a § 10(b) violation. Accordingly, the Court GRANTS Defendants' motion to dismiss this cause of action. Because Plaintiffs have previously been afforded leave to amend their complaint, the Court grants the motion without leave to amend. See Allen, 911 F.2d at 373-74.

CONCLUSION

For the reasons set forth above, the Court GRANTS Defendants' motion to dismiss the 2AC (Docket No. 51) in its entirety without

leave to amend. The Clerk of the Court shall enter judgment and close the file. The parties shall bear their own costs.

IT IS SO ORDERED.

Dated: November 10, 2015

CLAUDIA WILKEN
United States District Judge